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510(K) SUMMARY

INTEGRA™ Flowable Wound Matrix

OCT 10 2007

Submitter's name and address:

Integra LifeSciences Corporation
311 Enterprise Drive
Plainsboro, NJ 08536 USA

Contact person and telephone number:

Diana Bordon
Manager, Regulatory Affairs
Telephone: (609) 275-0500
Fax: (609) 275-9445

Date Summary was prepared:

July 27, 2007

Name of the device:

Proprietary Name:	INTEGRA™ Flowable Wound Matrix
Common Name:	Collagen Wound Dressing
Classification Name:	Not Classified
Product Code:	KGN

Substantial Equivalence:

INTEGRA™ Flowable Wound Matrix is substantially equivalent in function and intended use to INTEGRA™ Matrix Wound Dressing (K022127) and Medifil® Particles K910944.

Device Description:

INTEGRA™ Flowable Wound Matrix is an advanced wound care device comprised of granulated cross-linked bovine tendon collagen and glycosaminoglycan. The granulated collagen-glycosaminoglycan is hydrated with saline and applied in difficult to access wound sites and tunneled wounds. It provides a scaffold for cellular invasion and capillary growth. INTEGRA™ Flowable Wound Matrix is supplied sterile, in single use kits containing one syringe with granular collagen, one empty sterile syringe, one luer lock connector, and one flexible injector.

Intended Use:

INTEGRA™ Flowable Wound Matrix is indicated for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, skin tears) and draining wounds. The device is intended for one-time use.

Testing and Test Results:

Results of physical testing, biocompatibility studies and clinician evaluation have demonstrated the collagen-glycosaminoglycan matrix in INTEGRA Flowable Wound Matrix to be safe and effective for the management of wounds.

Conclusion:

INTEGRA Flowable Wound Matrix is safe and effective under the proposed conditions of use and substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Integra LifeSciences Corporation
% Ms. Diana M. Bordon
Manager, Regulatory Affairs
311 Enterprise Drive
Plainsboro, New Jersey 08536

OCT 10 2007

Re: K072113
Trade/Device Name: INTEGRA™ Flowable Wound Matrix
Regulatory Class: Unclassified
Product Code: KGN
Dated: July 31, 2007
Received: August 1, 2007

Dear Ms. Bordon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072113

Device Name: INTEGRA™ Flowable Wound Matrix

Indications For Use: INTEGRA™ Flowable Wound Matrix is indicated for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, skin tears) and draining wounds. The device is intended for one-time use.

Prescription Use _X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072113

Concurrence of CDRH, Office of Device Evaluation (ODE)